

**FAX**

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Date April 27, 2004 Pages including cover 6

Subject Reply Brief



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**APR 29 2004**

Serial No.: 10/007,272

Filing Date: October 29, 2001

Applicant: Glover et al.

Title: Novel Crystalline Forms of an Antiviral Benzimidazole Compound

**Attached:**

Transmittal Form w/Certificate of transmission via facsimilie  
Reply Brief

Thank you,  
Valerie Phillips

**CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8)**

Applicant(s): Glover et al.

Docket No.

PU3126US2

Serial No.

10/007,272

Filing Date

10/29/01

Examiner

Crane

Group Art Unit

1623

Invention: NOVEL CRYSTALLINE FORMS OF AN ANTIVIRAL BENZIMIDAZOLE COMPOUND

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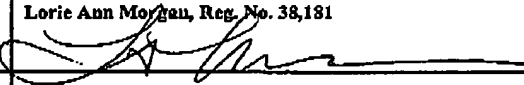


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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/007,272	
	Filing Date	10/29/01	
	First Named Inventor	Glover et al.	
	Art Unit	1624	
	Examiner Name	Crane	
Total Number of Pages in This Submission	6	Attorney Docket Number	FU3126US2

ENCLOSURES (check all that apply)		
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Remarks		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Lorie Ann Morgan, Reg. No. 38,181
Signature	
Date	27 April 2004

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APR 29 2004

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Patent Application of: Glover, et al.

Atty. Ref.: PU3216US2

Serial No.: 10/007,272

Group: 1623

Filed: 29 October 2001

Examiner: Crane

For: NOVEL CRYSTALLINE FORMS OF AN ANTIVIRAL BENZIMIDAZOLE COMPOUND  
\*\*\*\*\*Director of the U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

April 09, 2004

**OFFICIAL****REPLY BRIEF**

Further to the Examiner's Answer mailed 8 March 2004, Appellants respectfully request consideration of the following remarks in reply thereto.

Appellants respectfully submit that the Appeal Brief and the Examiner's Answer clearly express the respective positions of the parties on the outstanding section 102(e) rejection of Appellants' claims for compositions and methods of treatment comprising novel crystalline forms of a specific compound over the cited '832 patent. The key point of disagreement between the Examiner's position and the Appellants' position is whether the recited claim limitation of the specific crystalline form of the compound is relevant for differentiating the instantly claimed compositions and methods of treatment from compositions and methods of treating using the amorphous form of the compound that is described in the cited '832 patent.

The Examiner appears to believe it appropriate to disregard this admittedly recited claim limitation in the context of composition and method of treatment claims. Appellants respectfully maintain that it is improper for the Examiner to fail to consider any claim limitation. Appellants further respectfully submit that this limitation defines over the cited art ('832 patent) inasmuch as the '832 patent

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does not disclose or suggest the specific crystalline forms of the compound which are the subject of the Instantly pending claims.

Appellants further respectfully disagree with the Examiner's position that the instant application represent an unjust extension of the '832 patent. The pending claims require compositions comprising the specifically recited crystalline form of the compound and methods comprising administering the compound in the specifically recited crystalline form. Inasmuch as the claim limitations require the presence of a specific crystalline form of the compound, they do not encompass compositions or methods comprising non-crystalline forms of the compound. The Examiner's argument fails because a composition containing only the compound in solution does not fall within claim language inasmuch as it fails to include the recited crystalline form element of the claim. Similarly, what happens to the drug after ingestion is irrelevant because the claim requires that it is the recited crystalline form of the compound that is administered. One administering only the amorphous form of the compound does not meet the recited crystal form limitation of the claim. Consequently, the recited crystal form claim limitations do differentiate the instantly pending claims over the cited art and thus, the instant claims do not represented any unjust extension of the '832 patent.

The Examiner's Answer also states that Appellants have failed to point out any advantage of the recited crystalline form over the amorphous form of the compound disclosed in the '832 patent. Appellants respectfully direct the Boards attention to page 2, lines 1-8 of the original specification where the advantages of the specific crystal forms are set forth. Advantages include that they have improved thermodynamic stability, they are non-hygroscopic, they possess good storage properties, and they can be readily formulated into pharmaceutical compositions. Appellants respectfully note that these advantageous properties, together with the recited specific crystal form claim limitations were deemed to overcome a double patenting rejection over the '832 patent in the parent case (now USPN 6469160) which claims the same novel crystal forms of the compound which are at issue here.

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Appellants respectfully renew the request that the outstanding section 102(e) rejection be reversed.

Respectfully submitted,



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Date: 9 April, 2004  
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